Medical Expert Witness Report for v. Northeast Ohio Corrections Center

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I. Introduction

As a US board-certified physician in Internal Medicine, Pulmonary Disease, and Critical Care medicine, I am serving as a medical expert witness for the case of v. Northeast Ohio Correctional Center (NEOCC) regarding the risk of acquiring COVID19 illness and pneumonia. Please note that my comments are based on the medical records currently available to me.

II. COVID19 illness and pneumonia in adults

Definition

COVID19 stands for "Coronavirus Infectious Disease 2019" and denotes the set of primarily respiratory illnesses caused by the SARS-CoV2 virus (a member of the multitudinous coronavirus family) that were recognized in late 2019 during an outbreak in Wuhan, China. However, unlike other coronaviruses that primarily cause upper respiratory infections (e.g. HCoV 229E, NL63, OC43, and HKU1), SARS-CoV2 predominantly causes lower respiratory tract infection i.e. pneumonia. Like other viral syndromes, other organ systems can be affected, as SARS-CoV2 has been associated with gastroenteritis (with symptoms including nausea and diarrhea) (1), anosmia (loss of smell), and dysgeusia (altered taste) (2). Given the rapid global spread of the disease with associated high disease severity and mortality, COVID19 was declared a global pandemic on March 11, 2020 by the World Health Organization.

Pneumonia is defined as an infectious disease of the lung tissue usually due to bacteria (e.g. Streptococcus pneumoniae, Staphylococcus aureus, etc.) and/or viruses (like influenza, adenovirus, etc. – and now SARS-CoV2) and is commonly seen during clinical practice, accounting for over 4.5 million outpatient and emergency room visits and over 1.5 million hospitalizations per year in the United States (3). The figures cited above likely underrepresent the current state as they do not include the impact of the COVID19 pandemic, as COVID19 prevalence estimates are inaccurate due to limitations of testing and reporting (4,5).

Epidemiology

As data continues to demonstrate a rising number of cases and fatalities in the US, pneumonia from SARS-CoV2 continues to be a serious health concern. The Centers of Disease Control updates the number of COVID19 cases in the US daily (https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html), and as of April 18, 2020, the US has had a total of 690,714 cases and 35,443 deaths in 55 jurisdictions. In Ohio, there have been 10,222 cases, 451 deaths, and 760 ICU admissions. However, given limitations of testing, under-ascertainment is likely falsely depressing actual infection numbers. Furthermore, accurate details regarding the number of hospitalizations, exact mortality, and number of illnesses from COVID19 are not yet available (5).

While data are still evolving, there are several putative risk factors for development of COVID19 (6–9). Also, while studies need to be performed, it is plausible that several of these risk factors may be <u>additive</u> as regards risk, as in the case of non-COVID19 community-acquired pneumonia risk factors (10):

- Predisposing clinical conditions
 - Chronic lung disease, e.g. asthma, bronchiectasis, and particularly chronic obstructive pulmonary disease (i.e. emphysema)
 - Cardiovascular disease (coronary artery disease and heart failure)
 - Obesity, particularly BMI≥30. Patients who were < 60 years of age with BMI≥35 had a
 3.6 times higher risk of critical illness due to COVID (7)

- Hypertension
- o Diabetes mellitus
- Cancer
- Chronic kidney disease
- Immunosuppressed condition
- Liver disease
- Male gender
- Black race (11,12)
- Age

Data indicate that patients hospitalized with COVID illness have a median age of 49 to 56 years (1,13,14). Those who develop severe COVID19 illness are generally older, with existing data indicating that case fatality increases substantially after age 60, with estimated rates based on under-ascertainment of 0.32% for those age <60, 6.4% above age 60, and 13.4% above age 80 (15). US rates have comparably demonstrated poorer outcomes in older patients (16).

 Close contact in shared spaces and crowded living conditions without preventive infection control measures

While no empirical data yet exist, it is highly likely that inmates in correctional facilities will also demonstrate increased COVID19 infectious risk for several reasons. First, it is already well-known that inmates higher risk for developing various respiratory diseases such as pneumonia from influenza virus, adenovirus (17), Legionella sp., tuberculosis, and others (18), and COVID19 would be no exception to the rule. Second, the type and duration of exposure is an important factor in COVID19 transmission between persons. Higher rates of COVID19 disease spread have been documented in locations such as cruise ships, long-term care facilities, and even family gatherings (19–21). Similarly, and in some ways more so, frequent and close physical contact between inmates in shared spaces is common in a correctional facility, lending higher risk of transmission. Finally, the use of preventive infection control measure, a key factor in mitigating disease transmission, is often lacking in correctional facilities (18).

Pathogenesis

In all types of pneumonia, organisms (bacterial, viral, or other) cause direct injury to lung cells of the lower respiratory tract (particularly alveoli) that results not only in local disruption of cellular function but also systemic inflammatory effects, depending on the virulence of the organism and the integrity of host immune response. COVID19, like influenza and other viruses, commonly enter an individual via droplet inhalation into the upper respiratory tract (e.g. eye, nose, and throat) and subsequently move into the lower respiratory tracts by microaspiration or are directly inhaled into the lower airways.

Clinical Consequences of COVID19 pneumonia

COVID19 pneumonia has a wide spectrum of disease severity ranging from mild respiratory symptoms to frank respiratory failure, and predicting which exact patients will develop severe disease (and when) is still an active area of investigation. Respiratory organ failure often requires use of non-invasive (e.g. High Flow Nasal Cannula) as well as invasive forms of ventilatory support, i.e. with a mechanical ventilator, which lead to additional complications for maintenance of non-pulmonary organ function since such support often impairs physiologic process related to neurologic, musculoskeletal, cardiac, gastrointestinal, and other organ functions. Furthermore, many patients with COVID pneumonia demonstrate dysfunction of multiple organs, including the heart, kidneys, and blood coagulation (i.e. clotting) system such that other modalities such as dialysis (i.e. blood filtration of toxins through a cleansing machine) and use of anticoagulants (blood thinners) may be necessary. A "cytokine release syndrome" in which high degrees of inflammation in the body arise as a severe reaction to the viral infection lead to systemic consequences in other organs. Preliminary estimates of overall prognosis

suggest that a significant number of patients with critical illness from COVID19 who require support via a ventilator machine either may not survive or will require prolonged ventilatory support for weeks to months as part of recovery efforts (personal experience and personal communications with investigators from Wuhan, China).

In COVID19 pneumonia, a high degree of vigilance is necessary as many patients, especially those with risk factors, may rapidly deteriorate and require urgent institution of ventilator-based support. In addition, some patients with COVID19 pneumonia demonstrate a "biphasic" clinical course, in which an initial period of improvement is followed by subsequent clinical deterioration several days later. Further study is needed to determine whether this pattern is due to intrinsic qualities specific to SARS-CoV2 infection itself, but this phenomenon may be another similarity to other types of viral pneumonia in which a secondary or "post-viral" bacterial pneumonia can occur (due to favorable conditions for bacterial infection from lung damage caused by the initial viral infection). Complications such as postviral bacterial pneumonia often cause significant systemic consequences in themselves (e.g. septic shock) that can complicate and prolong existing efforts to recover patients from COVID19 illness. In fact, sepsis (i.e. systemic, multi-organ dysfunction due to uncontrolled infection) itself incurs a high risk of mortality and morbidity (22). Finally, pneumonia can cause notable physical and emotional distress due to the symptoms experienced. Given the extended recovery periods for many cases of severe COVID19 pneumonia, it is important to recognize the impact of "Post-ICU Syndrome," a well-recognized consequence of critical illness in which neurocognitive, psychiatric, and functional recovery can lag for months to years after the inciting critical illness (23).

III. Diagnostic approach to COVID19 respiratory illnesses

Upper Respiratory Tract Infections

Clinicians make a distinction between infections of the <u>upper</u> respiratory tract (e.g. rhinitis, sinusitis, etc.) and <u>lower</u> respiratory tract (bronchitis and pneumonia). Also known as the "common cold," infections of the upper respiratory tract involve respiratory structures of the head and neck above the level of the trachea such as the nasal passages ("rhinitis"), pharynx ("pharyngitis"), ear ("otitis"), larynx ("laryngitis"), sinuses ("sinusitis"), or multiple areas either concurrently or sequentially (e.g. "rhinosinusitis") (24). Upper respiratory infections are very common (affecting 1 in 7-8 individuals yearly in the United States), usually viral in origin (N.B.: up to 30% are due to <u>non-SARSCoV2</u> coronaviruses), and self-limited, generally resolving within 10 days with only supportive therapy. Patients may also demonstrate mild symptoms of malaise and fatigue, but fever is typically absent. In addition, specific symptoms attributed to the involvement of specific respiratory structures are often present. For example, nasal involvement causes symptoms of nasal congestion, "runny" nose, and stuffiness; sinus involvement causes purulent mucus discharge, headache, facial pressure; laryngeal involvement causes hoarseness or loss of voice; pharyngeal involvement causes sore throat; ear involvement can lead to sensations of ear fullness or hearing loss.

In terms of upper respiratory infectious symptoms to date, SARS-CoV2 has been associated more commonly with anosmia (loss of smell), and dysgeusia (altered taste) (2) and less commonly with headache, runny nose, and pharyngitis (sore throat) (25).

Lower respiratory tract infection

Infections of the lower respiratory tract, on the other hand, involve respiratory structures below the level of the larynx and predominantly involve bronchi ("bronchitis") or bronchioles and alveoli ("pneumonitis" or "pneumonia") (26). Given the continuity and similarity of respiratory tract physiology, upper respiratory infections may precede development of lower respiratory tract infections, leading to

some overlap of symptoms (e.g. persistence of headache or nasal congestion) – this is true in COVID19 as well. However, the hallmark feature of involvement of the lower respiratory tract is the presence of cough (with or without sputum) (27). Wheezing, rhonchi (secretions audible in large airways), and shortness of breath may also be present (and observable on physical examination by a clinical provider).

Typical symptoms associated with lower respiratory tract infection, including COVID19 pneumonia (1), include the following:

- Fevers, chills, body/muscle aches, fatigue
- Systemic symptoms (e.g. fevers, low blood pressure, elevated heart rate, confusion, chills, loss of appetite, weight loss, lightheadedness, etc.)
- Cough, with or without sputum production (e.g. green, brown, bloody)
- Rapid and/or labored breathing pattern

Pneumonia (bronchopneumonia)

In general, the diagnosis of pneumonia requires careful scrutiny of medical information and requires a high degree of clinical suspicion particularly in patients with notable risk factors (please see section on Epidemiology for risk factors currently associated with COVID19 pneumonia). While patients with COVID19 pneumonia have a wide variety of presentation and severity, including lack of symptoms (28), most individuals for whom pneumonia (particularly from COVID19) is suspected present to clinical providers with 1) respiratory symptoms, including cough (with or without sputum (phlegm)), difficulty breathing, "tightness" in the chest or discomfort when inhaling ("pleuritic chest pain"), and 2) systemic symptoms such as fever, malaise, fatigue, and loss of appetite.

Viral pneumonias typically do not lead to production of sputum unless a concurrent bacterial infection is also present. That being said, when sputum is present, clinicians should inquire whether patients have noted changes in sputum color, consistency, and quantity compared to prior (e.g. change in sputum from clear to yellow/green), which can indicate an evolving illness. Signs (i.e. physical examination-based findings) of pneumonia include fever, adventitial (abnormal) breath sounds (i.e. crackles, wheezes, rhonchi, or squeaks) on auscultation of the chest, tachycardia (high heart rate), tachypnea (high respiratory rate). In patients with intact and robust immune systems, "typical" bacterial pneumonias are more likely to present with higher fevers (>101 F or 38.5 C) than viral or other infectious pneumonias but this is not universal (N.B.: COVID19 patients often present with significant fevers, usually >100.4° F) and may be absent in older patients. It should be noted that while these symptoms and signs may be indicative of pneumonia, their sensitivity and specificity vary (i.e. other respiratory disorders may present with similar features), with no clear set of symptoms and signs that are pathognomonic for pneumonia (29). Indeed, one study showed that the combination of fever, cough, high heart rate, and crackles (a type of adventitial breath sound) had a sensitivity of <50% (30).

Certain populations may present further difficulties in diagnosis, particularly those with advanced age and compromised immune systems (31). For example, elderly patients with pneumonia may demonstrate symptoms that are either minimal to absent or nonspecific (e.g. reduced oral intake, incontinence, or decreased activity (32), without overt fever or recognizable respiratory symptoms (33). As a result, diagnosis can be challenging and a higher clinical suspicion is often necessary in such patients. For this reason, locations where older individual reside, such as long-term care facilities, are at especially high risk for undetected acquisition and spread of COVID19 disease (20).

Given the lack of reliable sensitivity of specificity of signs and symptoms, particularly in the immunocompromised and older populations, adjunctive diagnostic testing is necessary to make a diagnosis of pneumonia. Chest imaging (e.g. chest x-ray and/or CT scan) is essential, while laboratory

data (e.g. white blood cell count, serum procalcitonin level (34)) can also be helpful. Like symptoms and signs, however, these tests also demonstrate high sensitivity but not specificity for pneumonia and therefore other alternative diagnoses must always be considered. Imaging findings in COVID19 pneumonia vary considerably but often demonstrate multiple areas of bilateral (i.e. both lungs), peripheral, and ill-defined "ground glass" (i.e. hazy appearing) and/or consolidative (i.e. solid mass-like) opacification as is seen in other viral pneumonias (35). CT scans of the chest are usually not required unless chest x-ray findings are absent, equivocal, or lack sufficient detail for the clinician; CT scans provide a much higher degree of detail of the lung tissue and can assist in diagnostic and therapeutic approaches, depending on the severity of patient's clinical condition (e.g. identifying collapsed areas of lung or affected areas amenable to bronchoscopic intervention and/or sampling).

Outpatients with suspected COVID19 illness of mild severity usually do not receive additional testing and are managed empirically through self-isolation and following hygienic practices such as handwashing and nose and mouth covering (e.g. with masks) to prevent droplet dispersion when coughing or sneezing. On the other hand, patients with moderate or severe respiratory disease are often admitted to the hospital (especially those requiring intensive care unit admission) and receive additional microbiologic testing, including sputum analysis, blood cultures, urinary tests, and molecular methods (e.g. reverse transcriptase and other polymerase chain reaction assays, immunofluorescence, etc.) to identify putative organisms – particularly SARS-CoV2 given its virulence and urgency from a public health standpoint. The currently accepted microbiologic standard test for COVID19 is a reverse-transcriptase polymerase chain reaction (i.e. viral RNA genetic code-based amplification) biochemical test that is performed on specimens obtained by directly swabbing the nasopharyngeal mucosa (i.e. lining of the back of the nose and throat) or from sputum obtain from the lower respiratory tract (i.e. trachea or bronchi) in intubated patients or via bronchoscopy.

Ultimately, an astute clinician must perform a careful analysis of risk factors, symptoms, signs, and corroborative imaging and objective test findings to make a clinical diagnosis of COVID19 pneumonia. Microbiologic data (e.g. sputum culture (36)) may be helpful to rule out other causes of pneumonia, but causative pathogens are seen in less than 50% of cases of non-COVID19 pneumonia. Furthermore, expectorated sputum samples vary in quality such that invasive tests (e.g. bronchoscopy) may be required for adequate bronchial and alveolar sampling for adequate capture of suspected virulent organisms. Here too, yield may vary based on the quantity of specimen obtained, such that diagnosis of active infection requires quantitative burden of organisms to impute a clinically significant infection.

Special considerations in COVID19 pneumonia

Several points in the diagnosis of COVID19 pneumonia should be emphasized. First, as 81% of patients infected with COVID19 have mild symptoms (37), most will not access the medical system and therefore will not receive a discrete diagnosis. As a result, the true prevalence of COVID19 illness will continue to be underestimated. Second, COVID19 symptoms can be nonspecific, as any respiratory viral illness (including COVID19) can affect both upper and lower respiratory tracts, as noted above. Sensitivity and specificity of certain hallmark symptoms in COVID19 patients (e.g. anosmia, dysgeusia, nausea, diarrhea) have not been determined as data are still evolving. Third, viral coinfection has been recognized (i.e. COVID19 and other viruses causing infectious respiratory disease at the same time) such that attributable disease to COVID19 alone is difficult (38–40). Fourth, current microbiologic testing strategies are inadequate because 1) testing is not universally available due to backlogs and shortages (4), 2) sensitivity, specificity, and predictiveness of existing testing methods have not been established definitively and may not be consistent and/or validated between different lab vendors (41), 3) many providers incorrectly interchange serology-based (i.e. antibodies to SARS-CoV2) and RT-PCR-based (i.e. direct viral RNA replication) testing in order to diagnose active COVID19 disease, 4) proper testing

depends on operator technique (42), location of specimen sampling (43), and quality of specimen obtained, 5) the best timing of testing itself is not definitively determined given that RT-PCR may be more likely positive earlier rather than later in disease course, leading to concerns of false-negative test results (44).

For these reasons, current recommendations for making a putative diagnosis of COVID19 pneumonia are largely based on astute clinical suspicion by carefully integrating putative risk factors with clinical symptoms and signs of disease upon presentation to medical providers. Adjunctive testing such as imaging and microbiological testing is important but data on true sensitivity and specificity still need to be definitively determined.

IV. Therapeutic approach to COVID19 disease

Given that disease spread is primarily through person-to-person transmission like other viral respiratory diseases, two main approaches are recommended to address the COVID19 threat: 1) individualized treatment regimens based on probability of active COVID19 disease and actual disease severity, and 2) promotion of public health-based strategies to prevent and curtail person-to-person-based disease spread.

Individualized treatment strategies

Once the diagnosis of COVID19 pneumonia is suspected or confirmed, the severity of disease must be evaluated. A variety of scoring systems exists for all types of pneumonia, including CURB-65 (45), Pneumonia Severity Index (46), and SMART-COP (47), all of which address the risk for clinical deterioration and can help clinicians assess where treatment should take place (i.e. outpatient, hospital, or ICU setting). These scoring systems take into account certain risk factors for clinical deterioration (e.g. multi-organ inflammatory involvement, age, degree of compromised of respiratory function, number of lung regions affected, etc.) and are best used as supplementary tools to assist clinicians in the appropriate triage of the individual patient.

After determining the appropriate site of treatment, the cornerstone of treatment for most types of non-viral pneumonia involves appropriate choice of antimicrobial agent(s). At this time, treatment is almost completely supportive for COVID19 (as is the case for most viral pneumonias), and putative therapeutic medications-based strategies are all purely investigational. Many studies are now underway to evaluate the use direct antiviral agents (e.g. remdesivir, hydroxychloroquine, azithromycin, lopinavir/ritonavir, etc.) and inflammatory cytokine-mitigating strategies (e.g. steroids, anti-IL-6 cytokine agents, convalescent plasma, etc.) (48).

While antimicrobial medications may ultimately have a role in treatment, clinicians must use appropriate adjunctive measures in all cases (e.g. oxygen supplementation, intravenous fluid administration, etc.) to support pulmonary as well as non-pulmonary organ functions. A key element of the therapeutic plan is vigilance for signs of early clinical deterioration, particularly respiratory failure, which often requires quick intervention and expedient initiation of more aggressive therapy, including provision of non-invasive and invasive modalities of ventilatory support. Clinical course may demonstrate worsening, even after institution of proper and aggressive medical therapy, before improvement occurs. The importance of close clinical monitoring escalates as severity of illness increases, particularly in the first few days after symptom onset.

Prevention of COVID19 illness and spread of disease

From a population-based, public health perspective, consensus in the medical community has formed around the importance of decisive infection control-based actions to stop the spread of disease. Concerns continue to be high that the scale of affected individuals would not only cause widespread morbidity and mortality to US citizens but also potentially overwhelm the medical system given limitations in personalized protective equipment, ventilators, personnel, and hospital beds. Initial efforts in early March 2020 had been focused on "containing" the disease through screening and treating individuals at ports of entry into the US who had recently (within the prior 14 days) traveled to (or were in contact with individuals who had traveled to) highly affected ("Level 3 Travel Notice") areas, which included China, South Korea, Iran, and Italy. However, given evidence that such measures ultimately were not as effective as hoped, as COVID19 cases continued to appear in communities in the US and other countries without any overt exposure to affected individuals from outside the country, US efforts quickly turned to "mitigate" the disease through the adoption of infection control measures on a mass population scale. The objective has been both to protect healthcare workers from contracting the disease with the use of proper infection control techniques and to slow the rate of spread of the disease ("flatten the curve") and allow hospitals to treat afflicted individuals with adequate medical resources. These measures continue to focus on avoidance of contact with infected droplets through which the SARS-CoV2 virus transmits disease and include the following: proper hand sanitization techniques (e.g. >20 seconds of washing with soap and water or use of approved liquid hand sanitizers with >60% alcohol base), avoidance of touching the face and surfaces where infected droplets may have landed, appropriate use of approved personalized protective equipment (PPE) including facial masks, and practicing "social distancing" (e.g. self-isolation, reduction of all non-essential travel, and maintenance of at least 6 feet of physical distance between persons).

While data are still being collected such that definitive conclusions cannot yet be made, one consistent finding has emerged: locations in which infection control measures have not been adequately achieved, particularly where large numbers of individuals exist in close proximity, have been associated with higher rates of COVID19 disease spread. For example, high disease spread has been seen in a long-term nursing facility (20), cruise ship off Yokohama Japan (21), and even social gatherings (19) where there were a high density of individuals and a lack of appropriate infection control measures taken. Urban centers, where population density is high, have been some of the hardest hit areas in the US, including New York City, Detroit, Seattle, and New Orleans (49).

On the other hand, locations where infection control measures were effectively instituted and population density is lower, diminished rates of transmission have emerged (even when controlling for geographic differences in population density). California, where infection control measures like social distancing were enforced early, has shown substantially lower numbers of COVID cases and slower rates of spread of COVID disease compared to other states where such measures were instituted later: California has had 38 cases in California per 100,000 residents while the national average is 103 cases per 100,000 residents (49,50). While cases have been seen in all 50 states, rural areas of the US, where population density is lower, are generally less affected (5). The effectiveness of infection control techniques is also seen internationally, since adoption of proper infection control measures in Japan not only reduced COVID19 spread but was associated with a significantly reduced number of influenza cases compared to prior years (51). Again, it is premature to make definitive conclusions, but the data are highly indicative that infection control measures, when properly followed, are effective to control disease acquisition and prevent spread.

As a result, while urgent efforts to diagnose and individually treat COVID19 cases are ongoing, almost all US and international public health authorities have particularly focused attention on preventive, "upstream" efforts to reduce risk of developing COVID19 by reducing population density wherever

possible and instituting infection control measures as widely and as soon as possible. Strategies continue to center on enforcement of social distancing/physical isolation, hand hygiene, region-specific "lockdowns" of free movement of citizens and closure of "non-essential" businesses, and appropriate use of PPE, including use of facial masks in public spaces. For their part, employers of essential businesses have been instructed to engage in universal screening by employers of all employees for temperature and respiratory symptoms, given the ineffectiveness of self-monitoring and self-isolation exhortations that were first attempted. Indeed, the recommendation of masks has become stronger recently, given increasing data that demonstrate that individuals who are infected can transmit infection to others before developing symptoms themselves, after an average incubation period of 4-5 days (52,53).

Risk of COVID19 infection and spread in correctional facilities

Individuals in correctional facilities constitute a population at particularly high risk for acquiring and spreading infectious diseases like COVID19, given increased prevalence of putative medical risk factors for COVID19, high population density, frequent use of shared spaces, and longstanding history of challenges in infection control measures (18). Incarcerated individuals are known to have higher prevalence of infectious diseases such as Hepatitis C, tuberculosis, and HIV due in part to difficulties in mitigating disease transmission between communities and correctional settings. In addition, individuals in correctional facilities have higher rates of chronic disease (50% have at least one chronic disease), including higher rates of liver disease (~33%), an identified risk factor for COVID19 pneumonia (18,54).

The high risk of this population of disease development and transmission is directly due to the absence of appropriate infection control measures. As Bick (18) writes:

"Most jails and prisons were constructed to maximize public safety, not to minimize the transmission of disease or to efficiently deliver health care. The probability of transmission of potentially pathogenic organisms is increased by crowding, delays in medical evaluation and treatment, rationed access to soap, water, and clean laundry, insufficient infection-control expertise, and prohibitions against the use of proven harm-reduction tools ... The abrupt transfer of inmates from one location to another further complicates the diagnosis of infection, interruption of transmission, recognition of an outbreak, performance of a contact investigation, and eradication of disease... Some correctional facilities have been slow to seek assistance from outside agencies, and published guidelines for the diagnosis and treatment of communicable diseases are often not readily applicable to correctional facilities. Infection-control practitioners must be innovative in their efforts to protect the health of inmates and correctional employees."

The 2009 experience of H1N1 influenza pandemic in the prison population underlines the importance of this issue today, given that both COVID19 and influenza have both caused novel viral pandemics with similar modes of disease transmission. In the case of H1N1 influenza, prison populations were deemed to have high risk for disease transmission yet there were substantial delays in vaccine administration even for high risk individuals (e.g. pregnant inmates) (54,55). As a result, several recommendations have been made that draw from past experiences with the H1N1 influenza pandemic (see Figure 1) and directly relate to reducing risk of COVID19 disease today.

Impact of COVID19 mitigation in correctional facilities upon community spread of disease
Proper control of development and spread of COVID19 in correctional facilities not only serves the inmate population itself but also the communities around them, because employees and

staff/contractors frequently enter and leave the facilities to their home communities, families and friends of inmates and staff/contractors living in local and distant communities often make visitations to such facilities, and inmates themselves are often transported within, between, and out of such facilities. Person-to-person transmission of disease can occur at any of these touchpoints and can exacerbate efforts to control community spread of disease.

For these reasons, the urgency and salience of mitigation of COVID19 illness in correctional facilities cannot be underemphasized, given the impact to both the correctional system and the communities it serves. Current operational recommendations for correctional centers center around delaying viral entry into correctional settings, controlling infections already in circulation, and preparing for a high burden of disease. As Akiyama (54) writes, "The better the mitigation job done by legal, public health, and correctional health partnerships, the lighter the burden correctional facilities and their surrounding communities will bear."

Recommended strategies for mitigation of COVID19 in correctional facilities In the case of COVID19, recommended measures that should be initiated <u>immediately</u> include the following:

- 1. Reduction of current incarcerated population density (54)
 - Increase efflux through "decarceration" or release as many people as possible, particularly those with elevated risk factors for COVID19 disease and with minimal likelihood to commit additional crimes
 - Reduce influx through suspension of arrests and sentencing for low-level crimes and misdemeanors
- 2. Institution and enforcement of social distancing measures (56)
 - 6 feet mandatory minimum physical distance between all persons (inmates and staff/contractors) at all times
 - Reduction of common area activities where social distancing measures cannot be followed reliably
 - Replacement of in-person visitations with video-based visitations
 - Restricted and/or regulated access to vendors or suppliers to correctional facilities
- 3. Separation and isolation strategies for suspected and confirmed COVID+ patients away from general prison population
 - Single-cell housing wherever possible
 - Creation of wards where multiple confirmed mild COVID+ cases can be grouped
- 4. Active screening and surveillance of <u>all</u> inmates and staff/contractors for symptoms and signs of COVID19 illness
- 5. Active screening of <u>any</u> individual entering the correctional facility for symptoms and signs of COVID19 illness on each occasion
- 6. Access to medical care providers for urgent medical evaluation, testing, and hospitalization as indicated for any inmates and staff/contractors demonstrating active or equivocal symptoms or signs of COVID19 illness
- 7. Identification of staff/contractors infected previously who have fully recovered, deemed non-infectious, and can serve in various work capacities (e.g. custodial, other) to prepare for possible workforce shortfalls
- 8. Education around proper respiratory hygiene to all inmates and staff/contractors
 - Methods and rationale for appropriate use of PPE in all inmates and staff/contractors, particularly to those with respiratory symptoms (57)

- Reinforcement of appropriate cleaning methods and avoidance of surfaces that are potentially contaminated with infected bodily fluids
- Avoidance of touching the face, nose, and eyes in situations where possible contact with infected fluids exists
- 9. Reliable access to and adequate supplies of personalized protective equipment (of approved quality standards) for inmates and staff/contractors
 - Staff/contractors: CDC-approved surgical masks, N95 masks, droplet precaution gowns, gloves, face shields/goggles, antimicrobial cleaning supplies
 - Inmates: CDC-approved surgical masks, approved antimicrobial soaps and hand sanitizers (>60% alcohol based), sinks, showers, laundry, droplet precaution gowns, gloves, face shields/goggles, antimicrobial cleaning supplies
- 10. Institution of auditing and feedback from observation of staff workflows to ensure responsible and effective use of PPE and optimal supplies of PPE (58)

Subject	Comment(s)
Annual influenza vaccination of all inmates and employees	All employees and volunteers should be encouraged to receive annual influenza vaccination. Standing order programs should be used to increase vaccination levels. Offer vaccination during intake screening or en masse at the beginning of the influenza season.
Respiratory hygiene and cough etiquette programs	Educate inmates and employees concerning the importance of respiratory hygiene and cough etiquette throughout the influenza season. Ensure that supplies for hand washing are available where sinks are located. Consider additional measures, such as providing tissues and masks to inmates and employees who are coughing or sneezing so that they can cover their mouth and nose and providing tissues and alcohol-based hand rubs in common areas and waiting rooms.
Active surveillance and influenza testing for patients with new illness	Conduct surveillance for acute febrile respiratory illness and use rapid influenza testing and influenza cultures for prompt identification of outbreaks. Once an outbreak is identified, inform local and state health department officials within 24 h. Once an outbreak is confirmed, continue daily active surveillance for respiratory illness among inmates and employees until at least 1 week after the last confirmed influenza case is documented.
Use of standard and transmission-based (droplet) precautions	Standard precautions should be used during the care of all patients who have symptoms of a respiratory infection. In addition, droplet precautions should be used during the care of any patient who has suspected or confirmed influenza. Single-cell housing is recommended for patients who have suspected or confirmed influenza. If single-cell housing is not available, patients who have suspected or confirmed influenza should be cohorted. Surgical or procedure masks should be used when entering the patient's room or when working within 3 feet of the patient.
Additional infection-control measures during an outbreak	Cancel common activities. Limit movement within the facility. Suspend movement into and out of affected units
Transportation	Inmates who must be transported should wear a surgical or procedure mask.
Visiting	Inmates who have confirmed or suspected influenza should not participate in visiting. Persons who have respiratory symptoms should not be allowed to visit the facility
Administration of antiviral medications for prophylaxis and treatment	Use antiviral agents for treatment and prophylaxis of inmates and employees as per current guidelines.
Access to care	Liberalize access to medical care for inmates who have respiratory illnesses.

Figure 1. Key elements of an influenza prevention and control program for correctional facilities. From Bick (18).

V. Case discussion

The case of Mr. demonstrates several areas where the standard and recommended approaches for COVID19 diagnosis are not being met:

1. Failure of correctional facility to recognize the high prevalence of COVID19 in the Ohio prison system that necessitates urgent action to enforce mitigation measures

As reported in several news reports from April 20, 2020, Ohio has the highest number of COVID19 confirmed cases located in prison system in the US, (20% of 12,919 confirmed cases in the state), with one prison finding that 73% of its inmates were COVID19 positive (59,60). This high prevalence is highly likely to be replicated in many other prisons in Ohio and elsewhere, if and when testing becomes more available (4). Indeed, of the 3 people tested for COVID19 at NEOCC (2 staff members and 1 contractor), all 3 tested positive for the disease. It is only reasonable to suspect that if and when other persons are tested at the facility, they have a significant likelihood of testing positive as well.

2. Failure of correctional facility to recognize multiple risk factors for severe COVID19 disease in Mr.

The case of Mr. demonstrates several risks of contracting a severe illness due to COVID19. First, he is obese, with a BMI of 48, conferring a 3.6x risk of severe COVID19 disease in existing data (7). Second, he is an African-American male, which has been associated with substantially worse outcomes with COVID19 disease (11,12). Third, he has a high likelihood of asthma or other chronic respiratory disease, given his notable exposure to second-hand smoke throughout his childhood and young adult life. Fourth, although a proper workup is necessary, it is highly likely that like other obese Americans, Mr. has a diagnosis of "metabolic syndrome," a pro-inflammatory condition seen in obese individuals that is marked by insulin resistance (i.e. pre- or actual diabetes mellitus), hyperlipidemia (i.e. high blood fats), and cardiovascular disease (i.e. hypertension, coronary artery disease, heart failure) (61). Many of these features – obesity, diabetes, hypertension – are clear risk factors for severe COVID19 pneumonia based on current data as noted earlier in this report. As a result, Mr. faces a very high risk of severe COVID19 disease if he were to contract the illness.

3. Failure of correctional facility to confirm compliance with recommended actions to mitigate development and spread of disease

From the available information about NEOCC, existing documents and flyers appear to provide general information about guidelines related to COVID19 mitigation. However, there is little to no information about 1) how they specifically apply to the specific population of NEOCC, as details about COVID19 risk factors of these is unknown, and 2) how well these measures area being enforced. The following examples demonstrate that existing processes are inadequate:

- Per observations shared by staff at NEOCC to Mr. Carlos Warner (attorney), there are several clear violations of recommended COVID19 mitigation measures that either clearly violate NEOCC policies, increase risk for serious COVID19 disease, or both:
 - 1. Inmates are designated into 9 pods constituting 50-64 men in each pod.
 - 2. Inmates in 2-pod pairs (i.e. 100-128 men together) continue to engage in outdoor activities with close contact (e.g. exercise workouts, playing basketball, socializing, etc.) with only 2 out of 100 inmates wearing masks.
 - 3. Inmates in 2-pod pairs (i.e. 100-128 men together) travel together to meal distribution areas and sit together to share communal meals.

- 4. Attorneys are permitted to visit clients face-to-face without being required to use proper PPE or social distancing.
- 5. Neither PPE nor social distancing measures has been implemented in any visibly recognizable manner by inmates, staff, or contractors.
- 6. Staff employees have voiced confusion about both the use of PPE and social distancing measures due to mixed messages from NEOCC leadership, such that most employees understand all use of PPE to be completely <u>optional</u>. Furthermore, understanding of appropriate use of PPE and proper donning and doffing technique of PPE is poor.
- 7. Many NEOCC staff employees have admitted to not wearing appropriate PPE as directed.
- 8. Inmates are permitted to gather closely when medication distributions are held, indicating that social distancing measures are not being followed even for individuals with active medical conditions and illnesses.
- 9. Staffing shortages at NEOCC are due to employees staying home from work because of fear that has been heightened by mixed messages and a lack of transparency by NEOCC leadership surrounding COVID19.
- 10. There is systemic illicit drug use (particularly synthetic cannabinoids that are likely smoked) by inmates at NEOCC that includes as many has 50% of the inmate population, leading to concerns not only about violations of social distancing but also the likelihood of lung injury from consumption of the drug. Furthermore, staff employees are reportedly condoning these practices.
- 11. There is a lack of suitable medical personnel at NEOCC as several hospital staff have been sent home or isolated.
- 12. Several transport officers who were not equipped with appropriate PPE have tested positive for COVID19, and no known details exist regarding if and how screening, evaluating, or mitigation of direct contacts of these individuals took place
- 13. Inmates have not received any instruction on appropriate use of PPE or social distancing measures. Inmates had been issued one mask each, but compliance with appropriate mask wearing is estimated at 1-15%, with many masks either lost or discarded.

N.B. While the above points are difficult to corroborate at this time, the number, consistency, and content of the allegations make them credible and striking. They reveal an infection control program in disarray in a high risk environment and indicate a situation that is at best problematic and at worst dangerous for both staff and inmates.

- The CoreCivic document on Social Distancing is extremely vague, describing that "Those at Higher Risk" include persons "with underlying health conditions" and "weakened immune systems" but no other details are provided. The fact that many persons in incarcerated environments fall into these categories (i.e. 50% of incarcerated persons have at least one chronic disease and the prevalence of immune system-damaging conditions such as HIV and Hepatitis C is substantially higher in prison populations) is completely ignored. The document is more perfunctory rather than informative.
- The Entry Screening Process for Prevention of COVID19 Transmission lists outdated recommendations.

- Screening criteria referencing recent travel (in the last 14 days) are outdated and only allude to earlier policy-based attempts to "contain" the disease. Given the rising prevalence of COVID19 cases across the world, including the US, the current standard since mid March 2020 has been to "mitigate" the disease by <u>universal</u> screening measures, especially given the risk of asymptomatic transmission from person to person.
- 2. Current guidelines (for more than a month) have no longer favored categorizing countries according to travel risk (e.g. Level 3 Travel Notice Countries) since almost every country in the world has now had cases of COVID19. Instead, vigilance must be <u>universal</u> as infection is considered ubiquitous.
- 3. The 14 day timeframe has been discarded since cases have been accruing in the US since early March 2020, more than 6 weeks ago.
- 4. The use of a thermometer to detect temperature above 100.4 is listed as optional ("if thermometer is available" (sic)) in screening of employees, raising major questions about the seriousness of screening at NEOCC, since it is not clear how a fever were to be actually diagnosed if proper equipment is not used.
- The Infection Control Policy of NEOCC is inadequate.
 - The document provides only vague indications for reducing communicable disease spread related to respiratory viruses and makes no mention of specific measures related to the use of PPE control of respiratory viral diseases such as influenza, metapneumovirus, or COVID19.
 - The document does not contain details regarding droplet precautions that apply to
 respiratory virus containment such as seasonal or epidemic influenza strains (e.g. H5N1
 (CDC avian flu)) and COVID, which is not surprising since the document has not been
 updated since February 2016.
 - 3. It is not clear that NEOCC has enough "isolated cells" and/or "designated areas appropriate for the condition" per section C.2.a. for suspected or confirmed cases. Using projections based on Marion County, OH, in which 73% of inmates tested positive (NPR report), the estimated number of inmates that would be expected to test positive for COVID19 (using current inmate census of 1624) is 1624 x 73% = 1,185. These individuals would need to be placed into isolated cells or "designated areas," but it is unlikely that this scale of resources is realistically available at NEOCC.
 - 4. The document does not describe the characteristics and determinants of "designated areas appropriate for the condition" such that the existence and appropriate use of such areas is speculative at best.
- Lack of appropriate testing supplies. Given that even conservative estimates of individuals
 testing positive for COVID19 would be in the hundreds (based on the inmate census of 1624),
 having only 50 test kits on hand is woefully inadequate.
- The existence of only 4 medical observation beds and absence of an infirmary to address an
 inmate census of 1624, many of whom are at higher risk for severe COVID19 infection due to
 prevalence of chronic diseases is unsatisfactory for the projected need.

Cognitive biases and medical decision-making

It is surprising to see anyone make errors of such a fundamental nature. One can only speculate about the reasons for this, but the presence of cognitive biases should be strongly considered. Indeed, individuals across disciplines have been recognized to be susceptible to various cognitive biases in daily practice, including anchoring, representativeness, overconfidence, availability, and confirmation biases, even in medical settings (62). In this case, the decision makers at the NEOCC correctional facility in Ohio are demonstrating features of omission bias, anchoring, confirmation bias, representativeness bias, availability bias, premature closure, and visceral bias (countertransference). As a result, the NEOCC facility administration is inappropriately minimizing the risk of COVID19 in its facility, not just to inmates and staff/contractors but also the community at large.

VI. Conclusion

I have herein illustrated the salient features of COVID19 illness from diagnostic and therapeutic standpoints as they directly relate to the case of Mr. As discussed above, I conclude based on reasonable medical probability that the substandard approaches to diagnosis and mitigation strategies of COVID19 at NEOCC substantially increase the risk of Mr. to contract a severe case of COVID19, the consequences of which might be serious and/or fatal.

I reserve the right to amend and supplement the opinions expressed in this report and my opinions if other medical records or materials pertinent to the case become available.

I may use any of the following exhibits as a summary or in support of all of my opinions: (1) any of the materials, or excerpts therefrom, identified in this report and attachments; (2) excerpts from scientific articles or learned treatises; (3) demonstrative models; (4) exhibits used by defendants' experts, or other witnesses; and (5) Mr. medical records.

SUBMITTED BY:

Venktesh R. Ramnath, MD

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